

Pomalidomide REMS

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Welcome to the Pomalidomide REMS

The Pomalidomide REMS (Risk Evaluation and Mitigation Strategy) is a safety program that manages the serious risks of pomalidomide. The Pomalidomide REMS is required by the Food and Drug Administration (FDA).

Important information about pomalidomide and the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- Only prescribers and pharmacies certified by the Pomalidomide REMS can prescribe and dispense pomalidomide to patients.
- Patients must be enrolled in the Pomalidomide REMS and follow all the safety rules in the REMS order to receive pomalidomide.

Serious Risks of Pomalidomide:

- Birth defects (deformed babies) or death of an unborn baby
- Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism)

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Report adverse drug experiences that are suspected to be associated with the use of pomalidomide and any suspected pregnancy occurring during treatment with pomalidomide to the Pomalidomide REMS Coordinating Center by calling 1-866-245-7925, or to the FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional Pomalidomide REMS Information, please contact the Pomalidomide REMS at:

PHONE: 1-866-245-7925
FAX: 1-844-872-5446

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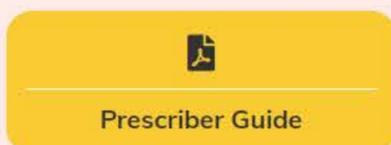
Prescribers

Key points of the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- The prescriber enrolls and becomes certified in the Pomalidomide REMS
- The prescriber counsels patient on benefits and risks of pomalidomide
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients who can get pregnant
- The prescriber completes a *Patient-Physician Agreement Form* with each patient and sends to the REMS Coordinating Center
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from the Pomalidomide REMS and receives confirmation that all REMS requirements have been met and is authorized to write the prescription and send to a Pomalidomide REMS certified pharmacy
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber must document the authorization number and patient risk category on each prescription
- The prescriber sends the pomalidomide prescription to a certified pharmacy

Learning more about the Pomalidomide REMS

For additional information about the Pomalidomide REMS, please see the educational materials below.



Enrolling in the Pomalidomide REMS

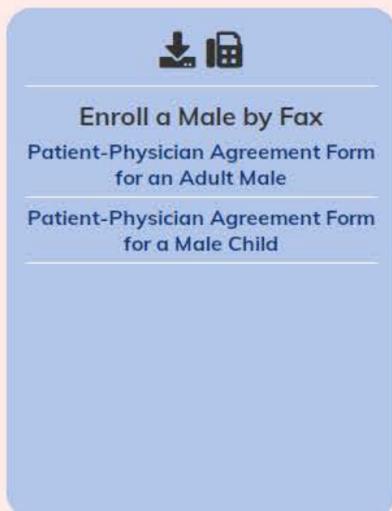
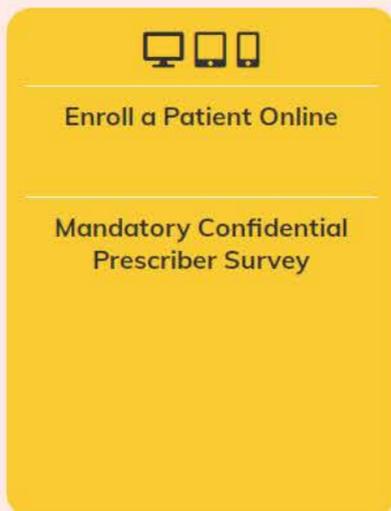
In order to prescribe pomalidomide, you must enroll in the Pomalidomide REMS and agree to follow the requirements of the program.

You can complete the *Prescriber Enrollment Form* online or download the *Prescriber Enrollment Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446.



Prescribing pomalidomide for your patients

In order to receive pomalidomide, your patients must also be enrolled in the Pomalidomide REMS. You can enroll your patients using the appropriate *Patient-Physician Agreement Form* available online or download the *Patient-Physician Agreement Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446. You and your patients can also complete your mandatory confidential surveys online or by telephone interview.



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Patients

What you need to know about the Pomalidomide REMS

Your doctor will enroll you in the Pomalidomide REMS so that you can receive your medication. Use the materials below to learn more about the Pomalidomide REMS, and what you need to do.

[Patient Guide](#)[Medication Guide](#)[Mandatory Confidential Patient Survey Online](#)[Emergency Contraception Brochure](#)

Attention Females Who Can Get Pregnant

Unless you abstain from sexual intercourse with a male partner, you are required to use **at the same time** at least 1 highly effective birth control method and at least 1 additional effective method **every time** you have sex with a male. Below, you will find a printable letter that you can bring with you to your next medical appointment that discusses your reproductive health. This will help you and your healthcare provider understand what types of birth control options are best for you.

[Birth Control Options to Discuss With Your Healthcare Provider](#)

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Patients

Mandatory Confidential Patient Survey

To begin, please enter your identifying information and click "Continue".

Patient Identifying Information

Your REMS ID was provided when you enrolled. If you do not have your REMS ID, or did not receive it, please contact the Pomalidomide REMS Coordinating Center by calling 1-866-245-7925.

Fields marked with an * are required.

*REMS ID

First Name

Last Name

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Mandatory Confidential Patient Survey

You are not required to submit a patient survey at this time. Your last submission was 99/99/9999. Your next survey can be completed beginning 99/99/9999.

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Mandatory Confidential Patient Survey

The survey you previously submitted did not meet the REMS requirements. Please contact your prescriber in order to retake the survey.

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Mandatory Confidential Patient Survey

Please read each question carefully and select your response.

Patient Identifying Information

REMS ID: 123456

First Name: Peggy

Last Name: Sue

Patient Initial Survey: Adult Female Who Can Get Pregnant

Fields marked with an * are required.

*Pomalidomide can cause severe birth defects or death to unborn babies of females taking pomalidomide.

True False

*Have you had both of your ovaries or your uterus surgically removed?

Yes No

*Have you been in natural menopause for at least 2 years?

Yes No

*What was the date of your last pregnancy test?

*What was the result of your last pregnancy test?

Positive Negative Cannot be determined Unknown

*Have you had sex with a male partner in the past 4 weeks?

Yes No

*If you are sexually active, are you aware of using 2 methods of birth control, as required for at least the past 4 weeks?

Yes No

*Have there been any instance of having sexual intercourse without using 2 forms of birth control?

Yes No

*Do you have any reason to think that you may be pregnant?

Yes No I am not sure

*Are you currently breastfeeding?

Yes No

*Will you return any unused pomalidomide to the pharmacy that dispensed the pomalidomide or to your prescriber for proper disposal?

Yes No

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Mandatory Confidential Patient Survey

Thank you for submitting the confidential Patient Survey. Your prescriber will be notified of the survey completion.

For more information please contact your prescriber or the Pomalidomide REMS by calling 1-866-245-7925.

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Patients

Mandatory Confidential Patient Survey

Thank you for submitting the confidential Patient Survey.

At least one of your answers did not meet the REMS requirements. Your prescriber may be contacting you to review your answers and will let you know when you should re-take the survey.

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Pharmacies

Key points of the Pomalidomide Risk Evaluation and Mitigation Strategy (REMS)

- The pharmacy certifies in the Pomalidomide REMS
- The certified pharmacy counsels the patient, and completes the *Education and Counseling Checklist for Pharmacies*
- The certified pharmacy must obtain a confirmation number from the Pomalidomide REMS Portal before dispensing
- The certified pharmacy dispenses pomalidomide to the patient along with a Medication Guide

Pomalidomide REMS information for certified pharmacies

Pomalidomide is only dispensed from Pomalidomide REMS certified pharmacies.

As a Pomalidomide REMS certified pharmacy, you must follow the requirements of the Pomalidomide REMS. You may enroll your pharmacy using the pharmacy enrollment form below. You can complete pharmacy enrollment online or download the *Pharmacy Enrollment Form* below and fax it to the Pomalidomide REMS at 1-844-872-5446.

[Enroll a Pharmacy Online](#)[Enroll a Pharmacy by Fax](#)

For more information on the Pomalidomide REMS, you can download the *Pharmacy Guide*, *Pharmacy Training* and the *Education and Counseling Checklist for Pharmacies*. Please also see the full prescribing information below.

[Pharmacy Guide](#)[Education and Counseling Checklist for Pharmacies](#)[Pharmacy Training](#)[Prescribing Information](#)

The Pomalidomide REMS Pharmacy Portal

Eligible pharmacies can obtain authorization numbers using the Pomalidomide REMS Pharmacy Portal.

[Log in to the Pomalidomide REMS Pharmacy Portal](#)

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Your username was supplied to you via email when you registered. If you need assistance, please call 1-866-245-7925.

Please enter your username

LOGIN

[Forgot Username](#)

OR

Do not have an online account?

Registration

To create your web account for the Pomalidomide REMS, please complete the fields below.

Fields marked with an * are required.

*NPI

*I am a

Prescriber Pharmacy

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Certified Pharmacy Lookup

Below is a list of all pharmacies dispensing pomalidomide

-  Download the list to spreadsheet format by clicking on the Excel icon just above the column headers
-  Search/Filter the list by entering information in the text box below any column header
-  Sort the list by clicking on any column header

			
Name 	Phone Number 	Fax Number 	Pharmacy Type 
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Testing Pharmacy	546-546-4545	564-564-5646	Inpatient

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List of products covered under the Pomalidomide REMS

Drug Name	Dosage	Company	Contact	Links
				Important Safety Information Prescribing Information Patient Medication Guide
				Important Safety Information Prescribing Information Patient Medication Guide

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Account Submitted Successfully

A confirmation of this submission has been sent to the email address provided. You can expect to receive 2 emails, one contains your username and the second contains your temporary password. Please login with the username provided. You will then be prompted to update your password.

If you do not receive the emails within the next few hours, or would like to update your enrollment information at any time, please contact the Pomalidomide REMS at 1-866-245-7925.

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